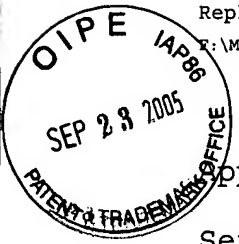


Application No. 10/062,178
Amdt. dated September 23, 2005
Reply to Office Action dated August 24, 2005
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Johann F. Hellenkamp

Serial No.: 10/062,178

Filing Date: January 31, 2002

For: IMPROVED AUTOMATIC SURGICAL DEVICE AND CONTROL
ASSEMBLY FOR CUTTING A CORNEA

Confirmation No. 9383
Thaler, M., Examiner
Group Art Unit 3731
Customer No. 04219

2800 S.W. Third Avenue
Historic Coral Way
Miami, Florida 33129
September 23, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE COMMUNICATION DATED 8/24/2005

Sir:

In response to the Office Action dated August 24, 2005, Applicant submits herewith an Amended Appeal brief in compliance with the requirements set forth by the Examiner.

The Commissioner is hereby authorized to charge and/or credit any fees under 37 CFR 1.16 and 1.17 which may be required by this paper to **Deposit Account No. 13-1227**. Please note that our Docket No. is 1.096.01.

Application No. 10/062,178

Amdt. dated September 23, 2005

Reply to Office Action dated August 24, 2005

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Respectfully submitted,

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Reg. No. 37,884

Date: 9/23/05

09-26-05

AF JFW



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Johann F. Hellenkamp

Serial No.: 10/062,178

Filing Date: January 31, 2002

For: IMPROVED AUTOMATIC SURGICAL DEVICE AND CONTROL
ASSEMBLY FOR CUTTING A CORNEA

2800 S.W. Third Avenue
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Dear Sir:

CERTIFICATE OF EXPRESS MAILING

I HEREBY CERTIFY that this correspondence is being deposited by United States Express Mail, Label No. EV-381-730-685-US, in an envelope addressed to: *Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450*, this 23 day of September, 2005.

Respectfully submitted,

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Date: 9/23/05



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)	
Johan F. Hellenkamp)	
Serial No.: 10/062,178)	Group Art Unit 3731
Filed: January 31, 2002)	Examiner: M. Thaler
)	Appeal No.
For: AUTOMATIC SURGICAL DEVICE)	
AND CONTROL ASSEMBLY FOR)	
CUTTING A CORNEA)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF OF APPELLANTS

This is an appeal from the final rejection of the Examiner dated December 9, 2004 rejecting claims 2-37, all of the claims in this case. This brief is accompanied by the requisite fee set forth in Rule 41.20(b)(2).

REAL PARTY IN INTEREST (37 C.F.R. 41.37(c)(1)(i))

The real party in interest in the present case based upon an exclusive license agreement from the named inventor is Bausch & Lomb, Inc.

RELATED APPEALS AND INTERFERENCES (37 C.F.R.

41.37(c)(1)(ii))

None.

STATUS OF CLAIMS (37 C.F.R. 41.37(c)(1)(iii))

The application was filed as a 37 C.F.R. Sec. 1.62 continuation application on January 31, 2002 with one (1) claim, which was an independent claim.

On February 12, 2003, an amendment before action was filed adding 37 claims, namely claims 2-38, of which 7 were independent.

Thereafter on December 30, 2003, a Second Preliminary Amendment Before Action was filed canceling claims 1 and 38. This cancellation left only claims 2-37, including 6 independent claims, pending for Examination.

All of the pending claims, namely claims 2-37, were rejected on June 21, 2004.

In Applicant's response of November 22, 2004, claims 2, 4, and 27 were amended.

The Examiner in the next office action of December 9, 2004, noted that the Applicant's arguments filed in the previous amendment were fully considered but were not

persuasive. Accordingly, pending claims 2-37 remain rejected, and are being appealed.

Claim 1. (Canceled)

Claim 2. (Presently Amended) A microkeratome cutting blade assembly for use with a surgical device that cuts at least partially across the cornea of an eye of a patient along an arcuate path, comprising:

a blade having a blade holder attached thereto;

said blade having a front portion and rear portion;

said front blade portion having a cutting edge for cutting a portion of the cornea of an eye;

said front portion having an overall dimension which is larger than the rear portion;

said blade having an edge for engaging said blade holder;

said blade holder having a top side and an underside said underside having a flanged portion which engages said edge whereby moving said blade holder correspondingly moves said blade; and

[said] an underside of said blade being inclined at an angle with respect to said top side, said top side adapted to be driven by a pin.

Claim 3. (Previously Presented) A microkeratome cutting blade assembly for use with a surgical device that cuts at least partially across the cornea of an eye of a patient along an arcuate path, comprising:

a blade having a blade holder attached thereto;

said blade having a front portion and rear portion;

said front blade portion having a cutting edge for cutting a portion of the cornea of an eye;

said front portion having an overall dimension which is larger than the rear portion;

said blade having an edge for engaging said blade holder; and

said blade holder having a top side and an underside, said underside having a flanged portion which engages said edge whereby moving said blade holder correspondingly moves said blade.

Claim 4. (Presently Amended) A microkeratome cutting blade assembly as recited in claim 3 wherein [said] an underside of said blade is [being] inclined at an angle with respect to said top side, said top side adapted to be driven by a pin.

Claim 5. (Previously Presented) A microkeratome cutting blade assembly as recited in claim 3 wherein said front blade portion has a front dimension and said rear blade portion has a rear dimension, said front dimension being wider than said rear dimension.

Claim 6. (Previously Presented) A microkeratome cutting blade assembly as recited in claim 5 wherein said front dimension of said front blade portion is defined by said cutting edge, which is wider than any dimension of said rear blade portion.

Claim 7. (Previously Presented) A microkeratome cutting blade assembly as recited in claim 3 wherein said blade holder is formed from a plastic material and is attached to said blade by a press fit.

Claim 8. (Previously Presented) A microkeratome cutting blade assembly for use with a microkeratome that cuts at least partially across the cornea of an eye along an arcuate path, comprising:

a blade having a blade holder attached thereto;

said blade having a front portion and a rear portion;

said front blade portion having a cutting edge for cutting a portion of the cornea of an eye;

said rear portion including a side edge
which is tapered with respect to said
cutting edge;

said blade holder having an underside
secured to said blade and a top side
including a recess adapted to receive an
oscillation pin.

Claim 9. (Previously Presented) A microkeratome cutting
blade assembly as recited in claim 8 wherein said
recess is structured to receive said oscillation
pin from a generally vertical plane.

Claim 10. (Previously Presented) A microkeratome cutting
blade assembly as recited in claim 8 wherein said
blade holder includes a sidewall which extends
between said top side and said underside, said
sidewall generally tapering from a front of said
blade holder to a back of said blade holder.

Claim 11. (Previously Presented) A microkeratome cutting
blade assembly as recited in claim 8 wherein said
blade further comprises an edge and said blade
holder comprises a flange for engaging said edge.

Claim 12. (Previously Presented) A microkeratome cutting blade assembly as recited in claim 8 wherein said tapered side edge comprises a generally linear taper.

Claim 13. (Previously Presented) A microkeratome cutting blade assembly as recited in claim 8 wherein said tapered side edge comprises a generally rounded taper.

Claim 14. (Previously Presented) A microkeratome blade assembly comprising: a blade holder and a cutting blade connected to said blade holder, wherein said blade holder includes a top side including means for being operably driven by an oscillating pin.

Claim 15. (Previously Presented) A microkeratome blade assembly as recited in claim 14 wherein said means for being operably driven comprise a recess.

Claim 16. (Previously Presented) A microkeratome blade assembly as recited in claim 14 wherein said blade is shaped so as to avoid interference with movement along an arcuate path when oscillated.

Claim 17. (Previously Presented) A microkeratome blade assembly as recited in claim 14 wherein said blade comprises a cutting edge, said cutting edge being wider than at least another portion of said blade.

Claim 18. (Previously Presented) A microkeratome blade assembly as recited in claim 14 wherein said blade further comprises at least four edges.

Claim 19. (Previously Presented) A microkeratome blade assembly as recited in claim 14 wherein said blade further comprises a front portion and a rear portion.

Claim 20. (Previously Presented) A microkeratome blade assembly as recited in claim 19 wherein said blade further comprises a side which tapers between said front portion to said rear portion.

Claim 21. (Previously Presented) A microkeratome blade assembly as recited in claim 19 wherein said front portion includes a cutting edge, said cutting edge of said front portion of said blade is wider than said rear portion.

Claim 22. (Previously Presented) A microkeratome blade assembly as recited in claim 14 wherein said blade further comprises an aperture, said blade holder secured to said blade at said aperture.

Claim 23. (Previously Presented) A microkeratome blade assembly as recited in claim 22 wherein said blade holder comprises a lock segment structured to extend into said aperture.

Claim 24. (Previously Presented) A microkeratome blade assembly as recited in claim 14 further comprising a handle removably connected to said blade holder.

Claim 25. (Previously Presented) A microkeratome blade assembly to be used with a microkeratome having a cutting head assembly that moves across a positioning ring, the microkeratome blade assembly comprising:

a blade holder and a cutting blade connected to said blade holder, said cutting blade shaped so as to avoid interference with movement of the cutting head assembly as said cutting blade

oscillates and moves across the positioning ring
along an arcuate path.

Claim 26. (Previously Presented) A microkeratome blade
assembly as recited in claim 25 wherein said
blade holder is structured to be operably driven
at a top side thereof.

Claim 27. (Currently Amended) A microkeratome blade
assembly as recited in claim[[s]] 25 wherein said
blade holder is structured to be operably driven
from a generally vertical orientation.

Claim 28. (Previously Presented) A microkeratome blade
assembly as recited in claim 25 wherein said
blade holder includes a recess structured to
receive a pin from a generally vertical
orientation.

Claim 29. (Previously Presented) A microkeratome blade
assembly as recited in claim 25 wherein said
blade comprises a cutting edge, said cutting edge
being wider than at least another portion of said
blade.

Claim 30. (Previously Presented) A microkeratome blade assembly as recited in claim 25 wherein said blade further comprises at least four edges.

Claim 31. (Previously Presented) A microkeratome blade assembly as recited in claim 25 wherein said blade further comprises a front portion and a rear portion.

Claim 32. (Previously Presented) A microkeratome blade assembly as recited in claim 31 wherein said blade further comprises a side which tapers between said front portion to said rear portion.

Claim 33. (Previously Presented) A microkeratome blade assembly as recited in claim 31 wherein said front portion includes a cutting edge, said cutting edge of said front portion of said blade is wider than said rear portion.

Claim 34. (Previously Presented) A microkeratome blade assembly as recited in claim 25 wherein said blade further comprises an aperture, said blade holder secured to said blade at said aperture.

Claim 35. (Previously Presented) A microkeratome blade assembly as recited in claim 34 wherein said

blade holder comprises a lock segment structured to extend into said aperture.

Claim 36. (Previously Presented) A microkeratome blade assembly as recited in claim 25 further comprising a handle removably connected to said blade holder.

Claim 37. (Previously Presented) A microkeratome blade assembly to be used with a microkeratome having a cutting head assembly that moves across a positioning ring, the microkeratome blade assembly comprising:

a blade holder; and

a cutting blade connected to said blade holder, said cutting blade shaped to provide clearance from the positioning ring as the microkeratome cutting blade assembly is oscillated such that said cutting blade will not interfere with movement of the cutting head assembly across the positioning ring along an arcuate path.

Claim 38. (Canceled)

STATUS OF AMENDMENTS (37 C.F.R. 41.37(c)(1)(iv))

No Amendment to the claims after final has been presented. Accordingly, the claims set out in the Appendix are in the form entered by the Amendment of November 22, 2004. An Amendment After Final has, however, been submitted simultaneously with this brief in order to address the Examiner's comments as to the claim of priority found in the patent specification, and place the case in better condition for appeal.

SUMMARY OF CLAIMED SUBJECT MATTER (37 C.F.R.

41.37(c)(1)(v))

The Applicant's invention is directed towards a Microkeratome Blade Assembly (105, 300), designed exclusively for use within a surgical instrument known as a microkeratome (10), and ideally within a microkeratome (10) that has been configured to travel along an arcuate path in order to form a corneal flap (F) with a superior hinge (Pg 27, Ln 24 - Pg 28, Ln 15). Specifically, a microkeratome (10) is a very high precision, ocular surgery, blade carrying device that must be manually pushed or mechanically driven in a cutting path across a suction ring simultaneous with the motorized movement of a cutting

element, which movement is transverse to the direction of the cutting path, in order to cut the cornea of a patient's eye (Pg 3 Lns. 12-16). The cut must necessarily be very precisely made, at least as to cut continuity and flap thickness, the normal tolerances being at the micron level. Failure to achieve the desired precision can result in eye damage, insufficient exposure of the underlying corneal tissue and/or other complications (Pg5 Ln 16 - Pg 6 Ln 8).

In practice, a microkeratome (10) includes a cutting head (50) that contains the blade (70, 71, 310, 310') that performs the actual cut (Pg 19 Lns 9-17). The cutting head (50) is structured to move in a precise and controlled fashion over the eye, typically over a positioning ring (32) that is secured to the eye and exposes the area to be cut. Whether this movement of the cutting head (50) across the positioning ring (32) is automated or manual, it is precisely controlled, maintaining a precise pre-defined path and a precise pre-defined spacing dictated by the structure and interconnection of the cutting head (50), blade (70, 71, 310, 310') and positioning ring (32). Freehand, unconstrained movement of the blade (70, 71, 310, 310') is never utilized and could not provide the precision

required. (Pg. 19 Ln 9 - Pg. 20, Ln 14) Moreover, the cutting head (50), typically through one or more gear structures and a drive (80) is configured to oscillate the blade (70, 71, 310, 310') as it is moving across the positioning ring (32) in order to achieve the best precision cut. (Pg 26 Lns 5-17)

The microkeratome blade assembly (105, 300) of the present invention is specifically configured to achieve the precision cut, and more importantly is structured to achieve the precision cut in a safe and stable manner while the cutting head (50) directs the blade (70, 71, 310, 310') along a desired path. (Pg 19 Ln 25 - Pg 20 Ln 14) In one embodiment of the microkeratome blade assembly (105, 300) the blade (70, 71, 310, 310') is precisely configured such that it will not interfere with or otherwise hinder or disrupt movement of the cutting head (50), and therefore the blade (70, 71, 310, 310') itself, along an arcuate path. (Pg 27 Ln 18 - Pg 28 Ln 15) For example, prior blade configurations were susceptible to disrupting and/or hindering the movement of the cutting head (50) as it followed the arcuate path due to the blade engaging the positioning ring (32) during oscillation to an extreme

lateral position. (Pg 27 Ln 18 - Pg 28 Ln 15) Because of the previously mentioned precision interaction between the cutting head (50) and the positioning ring (32), very small, tight tolerances are typically exhibited so that portions of the prior art blades could contact the positioning ring (32) resulting in the formation of metal particulates, and/or a disruption of the smooth continuous movement of the cutting head (50). Conversely, the first claimed embodiment of the microkeratome blade assembly (105, 300) is structured to eliminate this potential hazard.

In another embodiment of the claimed microkeratome blade assembly (105, 300), a blade holder (72, 320) is provided with means (325) at a top side (320) thereof to achieve driving of the blade by an oscillating pin (135). (Pg 28 Ln 16 - Pg 29 Ln 21) Unlike prior structures which have generally angled orientations susceptible to a cantilevering that could detach the blade from the eye, the second embodiment of the microkeratome blade assembly (105, 300) maintains certain extraneous structures, such as drive motors, cables, etc. in a vertically aligned orientation that minimize the risk of a cantilevered separation of the

blade from the eye, and which indeed help promote a constant and uniform downward pressure on the eye Pg 40 Ln 14 - Pg 41 ln 6).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

(37 C.F.R. 41.37(c)(1)(vi))

The Examiner has rejected pending claims 2-37 under 35 U.S.C. 102(b) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Mueller ("The Surgical Armamentarium").

1. It is the Examiner's contention that a specific illustrated scalpel blade and the associated scalpel handle disclosed in Mueller anticipate the Applicant's claimed invention. More particularly, the Mueller scalpel blade is relied upon to show all of the features of the Applicant's claimed blade, and the Mueller scalpel handle is relied upon to show all of the features of the Applicant's claimed blade holder. Moreover, and most significantly, the Examiner recites that: a) the Mueller Device (i.e. the combination of the scalpel blade and scalpel handle) "is **inherently** capable of being used to cut the cornea since it is a surgical blade, thus meeting the claimed term

'microkeratome'." (Page 4, 12/09/04 OA); and b) the Mueller scalpel blade/scalpel handle combination is **inherently** capable of being used to cut the cornea, or that in the alternative it would have been obvious to use the Mueller scalpel to cut the cornea since it is a surgical blade. (Page 3, 12/09/04 OA).

2. The Examiner recites that when the rear portion of the blade (i.e. the Mueller scalpel blade) is lifted relative to the blade holder (i.e the Mueller scalpel handle) as the blade is about to be detached from the blade holder, the combination scalpel blade and scalpel handle recite the claimed structure of "an underside of the blade being inclined at an angle with respect to the top side of the blade holder". (Page 3, 12/09/04 OA).

3. The Examiner contends that because the Mueller scalpel blade has a recess (apparently for gripping purposes as expressly pointed out by the Examiner) extending longitudinally along the handle, that recess is **inherently** capable of receiving a pin to move the scalpel handle, thus reciting the claimed language that the top side of the blade holder, which as previously recited has an underside of the blade angled with respect thereto, is

adapted to be driven by a pin. (Page 3, 12/09/04 OA). This same contention that the gripping recess is **inherently** capable of receiving a pin to move the Mueller scalpel handle is also relied upon to recite the claim language that the top side of the blade holder includes a recess. (Page 4, 12/09/04 OA).

4. The Examiner contends that the Mueller scalpel is "**inherently**" capable of avoiding interference with the movement of a cutting head assembly appropriately dimensioned, with regard to claim 25, which recites the 'cutting blade shaped so as to avoid interference with movement of the cutting head assembly as said cutting blade oscillates and moves across the positioning ring along an arcuate path.'

5. It is unclear where in Mueller support is achieved in connection with the claimed subject matter related to the blade holder or the recess in the blade holder being structured to be engaged from a vertical plane.

ARGUMENTS (37 C.F.R. 41.37(c)(1)(vii))

ISSUE 1

The rejection of all pending claims based upon Mueller's Surgical Armamentarium in that the Examiner

contends that a scalpel blade and scalpel handle are **inherently** capable of being used to cut the cornea since it is a surgical blade, thus meeting the claimed term 'microkeratome'.

Before addressing the Examiner's specific contention, it appears from the Examiner's comments that the Examiner is in agreement that "microkeratome" in the claim preambles is a limitation that must be considered. This is consistent with Federal Circuit precedent requiring that, in cases like this, where an Applicant's written description makes clear that the inventor was working on a particular problem, such as microkeratome cutting blade assemblies, and not on general improvements, such as to surgical blade assemblies generally, then the preamble gives "life and meaning" to the claims and therefore limits the claims to the particular problem. General Electric Co. v. Nintendo Co., 179 F.3d 1350, 1361-62 (Fed. Cir. 1999) ("Here, the '125 specification makes clear that the inventors were working on the particular problem of displaying binary data on a raster scan display device and not general improvements to all display systems. In light of the specification, to read the claim indiscriminately to

cover all types of display systems would be divorced from reality.") This is also consistent with the way two district courts have interpreted claims of Applicant's related U.S. Patent No. 6,051,009, including specifically claim 53 of the '009 patent which has the preamble "a microkeratome blade assembly comprising."¹ As such, the Applicant is of the opinion that the only point to be addressed in connection with this issue is the appropriateness of equating a scalpel to a microkeratome.

Along these lines, the Applicant respectfully urges that there are hundreds of different types of 'surgical blades' currently in uses throughout the many, different surgical arts. For example, biopsy probes of all sorts are fitted with 'surgical blades' to take samples and or remove tumors, motorized rotary saws having 'surgical blades' are provided to cut away bone, trocars used in laparoscopic surgery include removable 'surgical blades' to allow them to penetrate the patient's skin, etc. Because each of these blades must be sharp in order to fulfill their

¹ Memorandum of Decision Re: Claim Construction, CV 00-11298 MRP (C.D. Cal. Jul. 19, 2002) at p. 22, lines 18-22 (See. Second Supplemental IDS - Filed 8/6/03 - Data CD Ref #BLOM172); and Conclusions of Law Regarding Patent Claim Construction, CA No. 99-4247 (E.D. Pa. Apr. 16, 2002), p. 44, lines 4-10 (See. First Supplemental IDS - Filed 7/7/03 - Data CD Ref #BLMM59).

intended surgical purpose, they are, of course, capable of cutting many different parts of a patient's body, including the soft delicate structure of the eye. The mere capability to cut the eye and the fact that the blade is used in surgery, however, does not and could not be considered to meet the claimed term 'microkeratome'. The same is true for a common surgical scalpel such as that disclosed by Mueller.

The Mueller scalpel is a common surgical instrument that has a specific structure configured to allow a practitioner to grip it between their thumb and an opposing finger, and to push down into an object to a part of the body to be cut. Such a scalpel is not configured to provide any particular degree of precision beyond a comfortable feel that allows the practitioner to do their work and cut in a desired spot in a safe and detailed. Furthermore, such a scalpel is not configured to be positioned within a high precision device and moved along a pre-defined and precisely constrained path, nor is it configured or designed to achieve a cut having a very precise and controllable thickness within a small confined area of operation.

Accordingly, the Applicant urges that the field of art related to surgical scalpels has no bearing or structural similarity to the general field of art related to ocular surgery, let alone the even more specific field of art associated with microkeratomes. A person of ordinary skill in the microkeratome art would not look to the scalpel field of art to obtain solutions and/or improvements in their field, which has completely different constraints and considerations. Indeed, this is further compounded by the fact that the structure of the blade and handle in the scalpel art is most often dictated by comfort and feel in a practitioner's hands, and not by their interaction with a high precision device that will move in a specified manner to achieve a very precise, reproducible cut in a small, tight space and on a very delicate part of the body, namely the patient's eye. As a result, it is the Applicant's contention that the Mueller scalpel could not and would not anticipate, disclose or suggest, the Applicant's claimed Microkeratome Blade Assembly, and that as a result, the Examiner's basis for refusal as outlined in Issue 1 be withdrawn resulting in the allowance of pending claims 2-37.

ISSUE 2

The rejection of claim 2 and presumably claim 4 in view of Mueller based upon the contention that because the rear portion of the Mueller scalpel blade is lifted relative to the Mueller blade holder as the Mueller blade is about to be detached from the Mueller blade holder, the claimed structure related to an underside of the blade being inclined at an angle with respect to the top side of the blade holder, is anticipated.

With respect to this basis for rejection, the Applicant respectfully points out the Mueller blade is clearly intended for use while the handle and blade are in aligned relation with one another. The mere fact that the blade is possibly momentarily angled relative to the handle as it is attached or detached cannot be considered to anticipate, disclose or suggest the Applicant's claimed invention. In particular, claims 2 and 4 recite a specific operable structure wherein an underside of the blade is inclined at an angle with respect to the top side of the blade holder. This is the structure that must necessarily be maintained within those claimed embodiments in order for the microkeratome blade assembly to be effectively and

optimally used within a microkeratome, and Mueller contains no disclosure or suggestion of such structure. As a result, it is urged that claims 2 and 4 are in condition for allowance based upon these grounds as well.

ISSUE 3

The apparent rejection of claims 4, 8, 9, 14, 26 and 28, and accordingly also claims 10-13 that depend from claim 9 and claims 15-24 that depend from claim 14, based upon the Examiner's contention that a longitudinal gripping recess formed in the scalpel handle is **inherently** capable of receiving a pin to move the scalpel handle, thus reciting the Applicant's claimed language that the blade holder is structured to be driven at a top surface.

As pointed out by the Examiner, the recess in the Mueller scalpel handle appears to be for gripping. Specifically, it is a long tapered channel with an open front and open rear that gives added contour to the handle. In this regard, it is urged that not only would a person of ordinary skill in the art not look to a gripping recess in a scalpel handle for structure at which a microkeratome blade assembly is driven, but also, that the recited gripping recess could not function in such a manner.

Specifically, the open opposite ends of the recess and the angled side walls of the gripping recess would result in a non-uniform, unstable movement of the scalpel handle, and accordingly the scalpel blade which would be completely unacceptable in a high precision surgical field such as ocular surgery. Accordingly, it is urged that Mueller reference does not and could not anticipate the Applicant's claimed invention in this respect as well, and therefore, that claims 4, 8-24, 26 and 28 are further allowable on these grounds.

ISSUE 4

The rejection of claim 25 and accordingly claims 26-36 that depend therefrom, and the apparent rejection of claim 37 based upon the Examiner's contention that the Mueller scalpel is "**inherently**" capable of avoiding interference with the movement of a cutting head assembly appropriately dimensioned, and therefore recites the Applicant's claimed language for a cutting blade shaped so as to avoid interference with movement of the cutting head assembly as it moves across the positioning ring along an arcuate path.

With regard to this basis for rejection, the Applicant urges there is no teaching that the Mueller scalpel could

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or would be used with a microkeratome cutting head.

Furthermore, there is no way for the Mueller scalpel to be utilized with a microkeratome cutting head assembly, and even if some manner of use of the Mueller scalpel with a microkeratome cutting head were possible, any avoidance of interference would have to be dictated entirely by the position of the scalpel away from the cutting head, and not by its structure. Specifically, it is urged that nothing in the structure of the Mueller scalpel is configured for purposes of providing clearance, and especially not for providing clearance while it oscillates within a microkertome cutting head moving across a positioning ring across an arcuate path as claimed.

In particular, in the embodiment of claims 25 and 27, the Applicant's invention is expressly configured to oscillate and move along an arcuate path. Under such circumstances the microkeratome blade assembly is required to operate within the cutting head and turn, while oscillating, in such a manner that if an ordinary microkeratome blade assembly were utilized, the edges of the blade would scrape against or otherwise engage the positioning ring that constrains and guides the movement of the cutting head, thereby leading to disruptions in the

cutting process and/or the formation of metal fragments that could fall into the eye and damage the expensive, precision microkeratome.

Accordingly, it is believed that a person of ordinary skill in the art could not and would not look to the Mueller scalpel for any suggestion or motivation to provide a cutting blade that is structured to avoid interference with movement of the cutting head assembly as it moves across the positioning ring along an arcuate path. Therefore, the Mueller reference does not and could not anticipate the Applicant's claimed invention in this respect as well, and claims 16 and 25-37 are further allowable on these grounds.

ISSUE 5

The apparent rejection of claims 9, 27, and 28 with regard to the claimed subject matter that the blade holder or the recess in the blade holder are structured to be engaged from a vertical plane, in view of Mueller.

Although these claims, and more specifically the above limitation in these claims is not specifically addressed by the Examiner, they are rejected as part of the general rejection in view of Mueller. In this regard, however, the

Applicant is of the opinion that Mueller in no way discloses or suggests structure for driving or otherwise engaging a microkeratome blade assembly from a vertical plane. Indeed, even if the Mueller scalpel were positioned so that the elongate gripping recesses were positioned so as to be engaged from a vertical plane, such an orientation of the Mueller scalpel would render it inoperable. The Mueller scalpel, as with every other scalpel is configured to be used with the blade itself positioned in a generally vertical plane relative to the body part to be cut. Further, because the scalpel blade and scalpel handle are in the same parallel plane with one another when operatively connected (recall the Examiner's contention with regard to Issue wherein relative angling there between can be achieved only as the scalpel blade is being removed from the scalpel handle), the scalpel blade could not engage an underlying surface if positioned in such a manner so that the gripping recess was considered to be in a top surface.

Accordingly, a person of ordinary skill in the art seeking to solve the potential problem associated with tipping and/or cantilevering of a microkeratome cutting

head under the weight and manipulation of a vertical drive structure, would not find any motivation to look to a scalpel such as the Mueller scalpel to solve this problem, and even if they were to look to such a scalpel would find no teaching or suggestion of a way to solve the problem. It is therefore respectfully urged that claims 9, 27 and 28 are further allowable on these grounds as well.

GROUPING OF CLAIMS

As to claims 3, and 5-7, it is the Applicant's contention that issue 1 has bearing on independent claim 3 and accordingly claims 5-7 that depend therefrom. As such, claims 3, and 5-7 stand or fall together.

As to claim 2, it is the Applicant's contention that in addition to issue 1, issue 2 also has bearing, and as such, claim 2 stands or falls on its own.

As to claim 4, it is the Applicant's contention that in addition to issues 1 and 2, issue 3 also has bearing, and as such, claim 4 stands or falls on its own.

As to claims 8, 10-15 and 17-24, it is the Applicant's contention that in addition to issue 1, issue 3 also has bearing on independent claim 8 and accordingly claims 10-15

and 17-24 that depend therefrom. As such, claims 8, 10-15 and 17-24 stand or fall together.

As to claim 9, it is the Applicant's contention that in addition to issues 1 and 3, issue 5 also has bearing, and as such, claim 9 stands or falls on its own.

As to claim 16 and 26, it is the Applicant's contention that in addition to issues 1 and 3, issue 4 also has bearing, and as such, claims 16 and 26 stand or fall together.

As to claims 25, 29-36 and 37, it is the Applicant's contention that in addition to issue 1, issue 4 also has bearing on independent claims 25 and 37, and accordingly claims 29-36 that depend from claim 25. As such, claims 25, 29-36 and 37 stand or fall together.

As to claim 27, it is the Applicant's contention that in addition to issue 1, issues 4 and 5 also have bearing, and as such, claim 27 stands or falls on its own.

As to claim 28, it is the Applicant's contention that in addition to issue 1, issues 3, 4 and 5 also have bearing, and as such, claim 28 stands or falls on its own.

Accordingly, only claims 2, 4, 9, 27, and 28 stand on their own.

Furthermore, for convenience, the following listing is presented to clarify the applicability of each issue presented to the pending claims:

ISSUE 1 - All Claims. Claims 2, 3, 8, 14, 25 and 37 are independent and claims 4, 9, 27 and 28 are dependent claims that stand on their own.

ISSUE 2 - Claims 2 and 4. Claim 2 is independent and each claim stands or falls on its own.

ISSUE 3 - Claims 4, 8-24, 26 and 28. Claims 8 and 14 are independent claims and each of claims 4, 9 and 28 stand on their own.

ISSUE 4 - Claims 16 and 25-37. Claims 25 and 37 are independent claims and each of claims 27 and 28 are dependent claims that stand on their own.

ISSUE 5 - Claims 9, 27, and 28. Each of these claims are dependent claims that stand on their own.

Finally, it is noted that the groupings presented herein are provided solely for purposes of this Appeal.

APPENDIX - Claim Pending in Appeal (37 C.F.R.

41.37(c)(1)(viii))

2. A microkeratome cutting blade assembly for use with a surgical device that cuts at least partially across the cornea of an eye of a patient along an arcuate path, comprising:

a blade having a blade holder attached thereto;
said blade having a front portion and rear portion;
said front blade portion having a cutting edge for cutting a portion of the cornea of an eye;
said front portion having an overall dimension which is larger than the rear portion;
said blade having an edge for engaging said blade holder;
said blade holder having a top side and an underside
said underside having a flanged portion which engages said edge whereby moving said blade holder correspondingly moves said blade; and
an underside of said blade being inclined at an angle with respect to said top side, said top side adapted to be driven by a pin.

3. A microkeratome cutting blade assembly for use with a surgical device that cuts at least partially across the cornea of an eye of a patient along an arcuate path, comprising:

a blade having a blade holder attached thereto;
said blade having a front portion and rear portion;
said front blade portion having a cutting edge for cutting a portion of the cornea of an eye;
said front portion having an overall dimension which is larger than the rear portion;
said blade having an edge for engaging said blade holder; and
said blade holder having a top side and an underside, said underside having a flanged portion which engages said edge whereby moving said blade holder correspondingly moves said blade.

4. A microkeratome cutting blade assembly as recited in claim 3 wherein an underside of said blade is inclined at an angle with respect to said top side, said top side adapted to be driven by a pin.

5. A microkeratome cutting blade assembly as recited in claim 3 wherein said front blade portion has a front

dimension and said rear blade portion has a rear dimension, said front dimension being wider than said rear dimension.

6. A microkeratome cutting blade assembly as recited in claim 5 wherein said front dimension of said front blade portion is defined by said cutting edge, which is wider than any dimension of said rear blade portion.

7. A microkeratome cutting blade assembly as recited in claim 3 wherein said blade holder is formed from a plastic material and is attached to said blade by a press fit.

8. A microkeratome cutting blade assembly for use with a microkeratome that cuts at least partially across the cornea of an eye along an arcuate path, comprising:

- a blade having a blade holder attached thereto;
- said blade having a front portion and a rear portion;
- said front blade portion having a cutting edge for cutting a portion of the cornea of an eye;
- said rear portion including a side edge which is tapered with respect to said cutting edge;
- said blade holder having an underside secured to said blade and a top side including a recess adapted to receive an oscillation pin.

9. A microkeratome cutting blade assembly as recited in claim 8 wherein said recess is structured to receive said oscillation pin from a generally vertical plane.

10. A microkeratome cutting blade assembly as recited in claim 8 wherein said blade holder includes a sidewall which extends between said top side and said underside, said sidewall generally tapering from a front of said blade holder to a back of said blade holder.

11. A microkeratome cutting blade assembly as recited in claim 8 wherein said blade further comprises an edge and said blade holder comprises a flange for engaging said edge.

12. A microkeratome cutting blade assembly as recited in claim 8 wherein said tapered side edge comprises a generally linear taper.

13. A microkeratome cutting blade assembly as recited in claim 8 wherein said tapered side edge comprises a generally rounded taper.

14. A microkeratome blade assembly comprising: a blade holder and a cutting blade connected to said blade holder, wherein said blade holder includes a top side

including means for being operably driven by an oscillating pin.

15. A microkeratome blade assembly as recited in claim 14 wherein said means for being operably driven comprise a recess.

16. A microkeratome blade assembly as recited in claim 14 wherein said blade is shaped so as to avoid interference with movement along an arcuate path when oscillated.

17. A microkeratome blade assembly as recited in claim 14 wherein said blade comprises a cutting edge, said cutting edge being wider than at least another portion of said blade.

18. A microkeratome blade assembly as recited in claim 14 wherein said blade further comprises at least four edges.

19. A microkeratome blade assembly as recited in claim 14 wherein said blade further comprises a front portion and a rear portion.

20. A microkeratome blade assembly as recited in claim 19 wherein said blade further comprises a side which tapers between said front portion to said rear portion.

21. A microkeratome blade assembly as recited in claim 19 wherein said front portion includes a cutting edge, said cutting edge of said front portion of said blade is wider than said rear portion.

22. A microkeratome blade assembly as recited in claim 14 wherein said blade further comprises an aperture, said blade holder secured to said blade at said aperture.

23. A microkeratome blade assembly as recited in claim 22 wherein said blade holder comprises a lock segment structured to extend into said aperture.

24. A microkeratome blade assembly as recited in claim 14 further comprising a handle removably connected to said blade holder.

25. A microkeratome blade assembly to be used with a microkeratome having a cutting head assembly that moves across a positioning ring, the microkeratome blade assembly comprising:

a blade holder and a cutting blade connected to said blade holder, said cutting blade shaped so as to avoid interference with movement of the cutting head assembly as said cutting blade oscillates and moves across the positioning ring along an arcuate path.

26. A microkeratome blade assembly as recited in claim 25 wherein said blade holder is structured to be operably driven at a top side thereof.

27. A microkeratome blade assembly as recited in claim 25 wherein said blade holder is structured to be operably driven from a generally vertical orientation.

28. A microkeratome blade assembly as recited in claim 25 wherein said blade holder includes a recess structured to receive a pin from a generally vertical orientation.

29. A microkeratome blade assembly as recited in claim 25 wherein said blade comprises a cutting edge, said cutting edge being wider than at least another portion of said blade.

30. A microkeratome blade assembly as recited in claim 25 wherein said blade further comprises at least four edges.

31. A microkeratome blade assembly as recited in claim 25 wherein said blade further comprises a front portion and a rear portion.

32. A microkeratome blade assembly as recited in claim 31 wherein said blade further comprises a side which tapers between said front portion to said rear portion.

33. A microkeratome blade assembly as recited in claim 31 wherein said front portion includes a cutting edge, said cutting edge of said front portion of said blade is wider than said rear portion.

34. A microkeratome blade assembly as recited in claim 25 wherein said blade further comprises an aperture, said blade holder secured to said blade at said aperture.

35. A microkeratome blade assembly as recited in claim 34 wherein said blade holder comprises a lock segment structured to extend into said aperture.

36. A microkeratome blade assembly as recited in claim 25 further comprising a handle removably connected to said blade holder.

37. A microkeratome blade assembly to be used with a microkeratome having a cutting head assembly that moves across a positioning ring, the microkeratome blade assembly comprising:

a blade holder; and

a cutting blade connected to said blade holder, said cutting blade shaped to provide clearance from the positioning ring as the microkeratome cutting blade assembly is oscillated such that said cutting blade will not interfere with movement of the cutting head assembly across the positioning ring along an arcuate path.

The Commissioner is hereby authorized to charge all additional filing fees that may be required by the filing of this paper to our **Deposit Account No. 13-1227.**

Respectfully submitted,
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